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By: NFO/CPU/scs

SMM&N File No. 216644US0
Serial No.: 09/995,599
In the matter of the Application of: Masayasu OGUSHI, et al.
For: ENDOTRACHEAL TUBE

Due Date: 11/14/04

The following has been received in the U.S. Patent Office on the date stamped hereon:

- Dep. Acct. Order Form
- PTO Transmittal Letter
- Amendment After Final Rejection w/attachment
  - Declaration Under 37 C.F.R. §1.132 (executed, 4 pages)

Docket No. 216644USO

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In Re Application of	:	
Masayasu OGUSHI, et al.	:	Group Art Unit: 1772
Serial No.: 09/995,599	:	
Filed: November 29, 2001	:	Examiner: W. AUGHENBAGH
For: ENDOTRACHEAL TUBE		

DECLARATION UNDER 37 C.F.R. 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313-1450

Sir:

I, Yukihiro FUJIEDA, residing at Kurashiki-shi, Okayama-ken, Japan, hereby declares and states that:

1. I am one of the co-inventors of U.S. Application Serial No. 09/995,599 filed on November 29, 2001. I am thoroughly familiar with the contents of said Application, its prosecution before the United States Patent and Trademark Office and the references cited therein.

2. I am a graduate of Kyushu University, Department of Engineering, and received my Master's degree in the year 1989.

3. I have been employed by Kuraray Co., Ltd. in the year 1989 as a researcher in the field of medical equipment.

4. The following experiments were conducted by myself or under my direct supervision and control in order to prove that the endotracheal tube of the present

invention is superior in transparency to an endotracheal tube in which an ethylene/propylene copolymer as disclosed in US 6,184,291 B1 is used.

EXPERIMENTAL:

Experiments 1-3

The same procedures of Examples 1 to 3 as disclosed at page 20, lines 14-16 of the present specification were carried out to give a resin composition.

The resin composition was kneaded with an extruder (ϕ 40mm) at a resin temperature of 200°C and at 50 rpm, and extruded from the extruder to give a pellet having a diameter of 3 mm and a length of 3 mm.

The pellet was molded into a film having a thickness of 0.5 mm by heating the pellet at a temperature of 240°C with a hot pressing machine.

Comparative Experiments 1-3

The same procedures as in Experiments 1-3 were repeated to give a film having a thickness of 0.5 mm, except that an ethylene/propylene copolymer commercially available from Mitsui Chemical Company under the trade name of TAFMER P0480 was used in place of the polypropylene.

RESULTS:

As a physical property of the films obtained in Experiments 1-3 and Comparative Experiments 1-3, transparency of the film was evaluated.

The transparency of the film was evaluated by measuring a haze value of each film three times with a hazemeter in accordance with JIS (Japanese Industrial Standard) K7136-2000, and obtaining the average of the haze values in each film as a found value. The results are shown in the following Table I.

Table I

Experiment No.	Polyolefin (% by weight)		Styrenic elastomer (Resin 4) (% by weight)	Transparency (haze value)
	Polypropylene (Resin 1)	Ethylene/propylene copolymer (TAFMER P0480)		
1	40	-	60	7.2
2	30	-	70	4.2
3	20	-	80	2.0
Comp. Ex. No. 1	-	40	60	62.4
2	-	30	70	48.3
3	-	20	80	35.0

(Note) The smaller the haze value is, more transparent the sample film is.

DISCUSSION:

(1) When the polypropylene is used as a polymer (Experiments 1-3), as is clear from the results shown in Table I, an endotracheal tube having excellent transparency can be obtained because the film has high transparency.

(2) On the contrary, when the ethylene/propylene copolymer is used as a polymer (Comparative Experiments 1-3), as is clear from the results shown in Table I, an endotracheal tube having poor transparency can be obtained because the film is poor in transparency.

(3) The reason why the polypropylene gives an endotracheal tube excellent transparency will be based upon that the polypropylene exhibits excellent compatibility with the styrenic elastomer as compared with the ethylene/propylene copolymer.

(4) However, USP 6,184,291 B1 does not disclose or suggest that the combined use of the polypropylene and the styrenic elastomer gives an endotracheal tube excellent transparency.

Therefore, there is no motivation in USP 6,184,291 B1 to arrive at the present invention.

5. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

6. Further declarant saith not.

Yukihiro Fujieda

Yukihiro FUJIEDA

October 5, 2004

Date